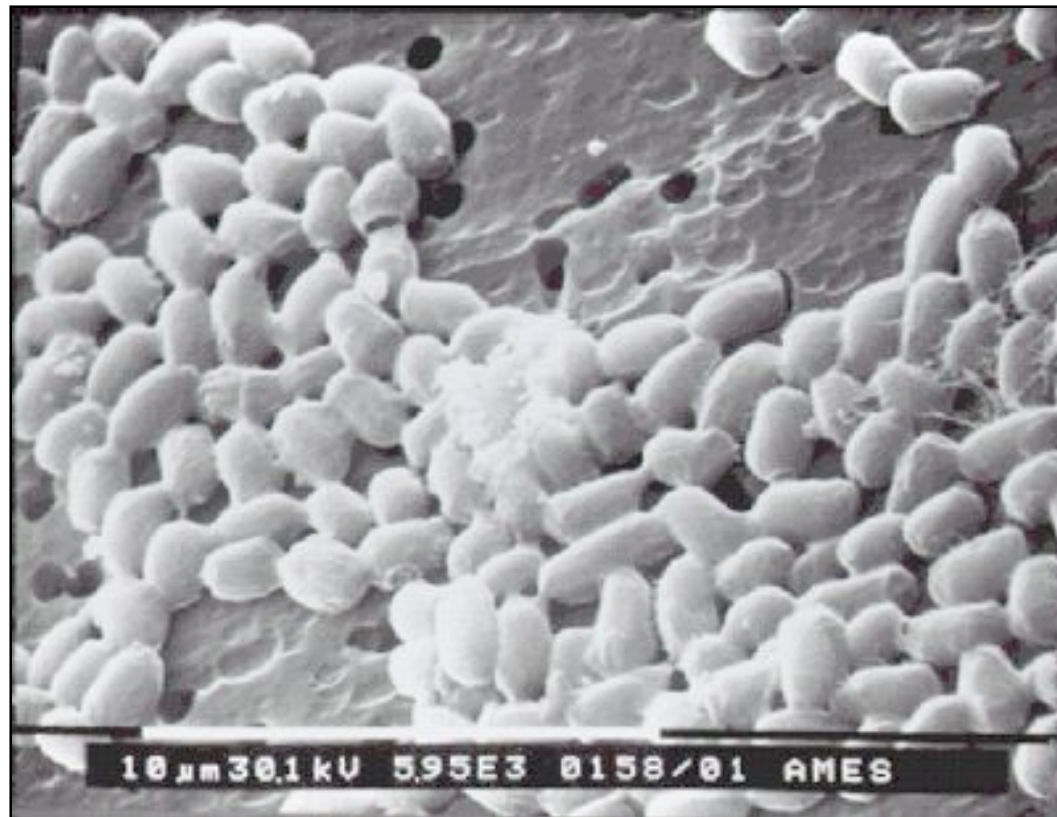


# Regulating Biological Agents: Balancing Security and Bio- Medical Research



Charles Vidich, Harvard School of Public Health  
[cvidich@hsph.harvard.edu](mailto:cvidich@hsph.harvard.edu)

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# Overview

- Why Congress tightened bio-agent rules
- Key legislation
- Who's in charge of bio-agent regulation
- Criteria for bio-agent controls
- Impacts on academic & public health labs
- Impacts on public health priorities
- Conclusions
- Policy alternatives and recommendations

# Why Have Biological Agents Become a Big Deal?

- **1996 mail order plague – Larry Wayne Harris**
  - “Do it Yourself” approach to plague research
  - Led to new law on transfer/use of bio-agents
- **2001 anthrax mailed to politicians & media**
  - Triggered massive ongoing investigation
  - Led to new laws on possession of bio-agents
  - Military labs implicated as possible source for agents

# Legislation –Biological-agents

- **Antiterrorism & Effective Death Penalty Act of 1996**
  - Governs transfer and use of bio-agents
- **USA PATRIOT Act of 2001**
  - Prohibits restricted persons from lab work
- **Public Health Security & Bio-terrorism Preparedness Response Act of 2002**
  - Governs bio-agent possession, lab security, bio-safety, training, inspections and notifications.

# Why Did Congress Increase Regulation of Biological Agents?

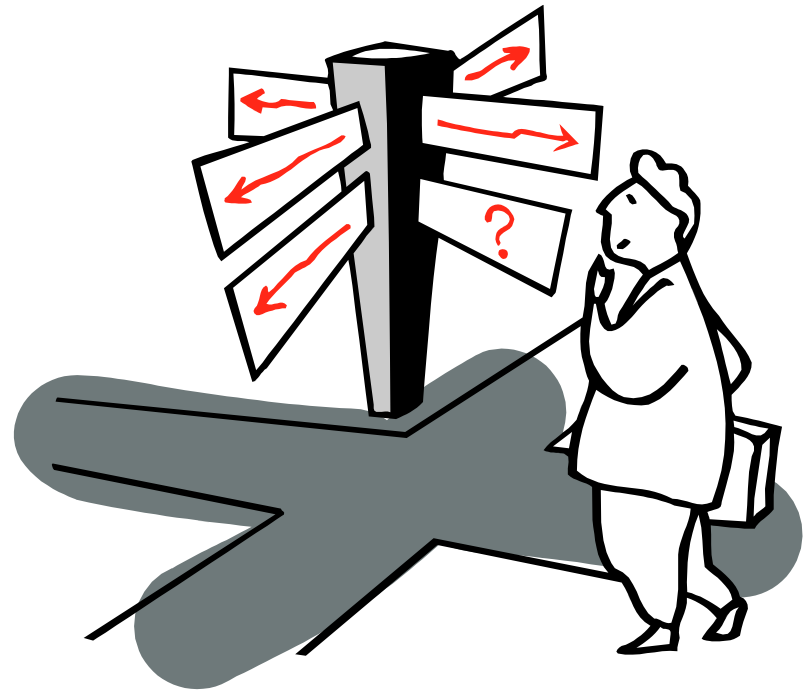
- **Assumption 1:** Increased lab security will reduce improper use of bio-agents for terrorism.
- **Assumption 2:** Increased inventory controls will allow for rapid tracking of misused bio-agents.
- **Assumption 3:** Security clearances for lab workers handling bio-agents minimizes risks of their misuse.

# Were The Assumptions Congress Made Correct?

- **Alternative Hypothesis 1:** Increased lab security may have no impact on improper use of bio-agents for terrorism.
- **Alt. Hypothesis 2:** Increased inventory controls of reproducible bio-agents doesn't guarantee misused bio-agents can be tracked.
- **Alt. Hypothesis 3:** Security clearances for lab workers may discourage legitimate scientists from pursuing bio-agent work.

# Who's in Charge of Select Biological Agent Work?

- Responsibility depends on the Issue
- Who's in charge varies by issue.
- Multiple federal Laws govern laboratory work.





# Select Agent Regulatory Issues:

## Who Governs What?

● = Pre 2001  
● = Post 2001

Laboratory Issues	DOJ	ICE	CDC	GAO	FBI	DOT	DHS
Restricted Persons	●		●		●		●
Visa controls		●					●
Responsible Official	●		●	●			
Criminal Investigations	●			●	●		
Restricted Biologic Agents			●		●		●
Focus on Bio-agent Research			●		●		●
Monitor Sensitive Research	●		●		●	●	●
Transport Controls						●	
Laboratory Security	●		●	●	●		●
Security/Emergency Plans			●	●	●		●

# Who's Affected by the Rules?

1,653 labs admit possessing select agents

But only 817 are expected to register

- Public health labs – 98 in Laboratory Response Network (LRN)
- Academic/non-profit labs – 344 affected.
- Commercial labs – 375 affected.



# What will the new Rule Cost?

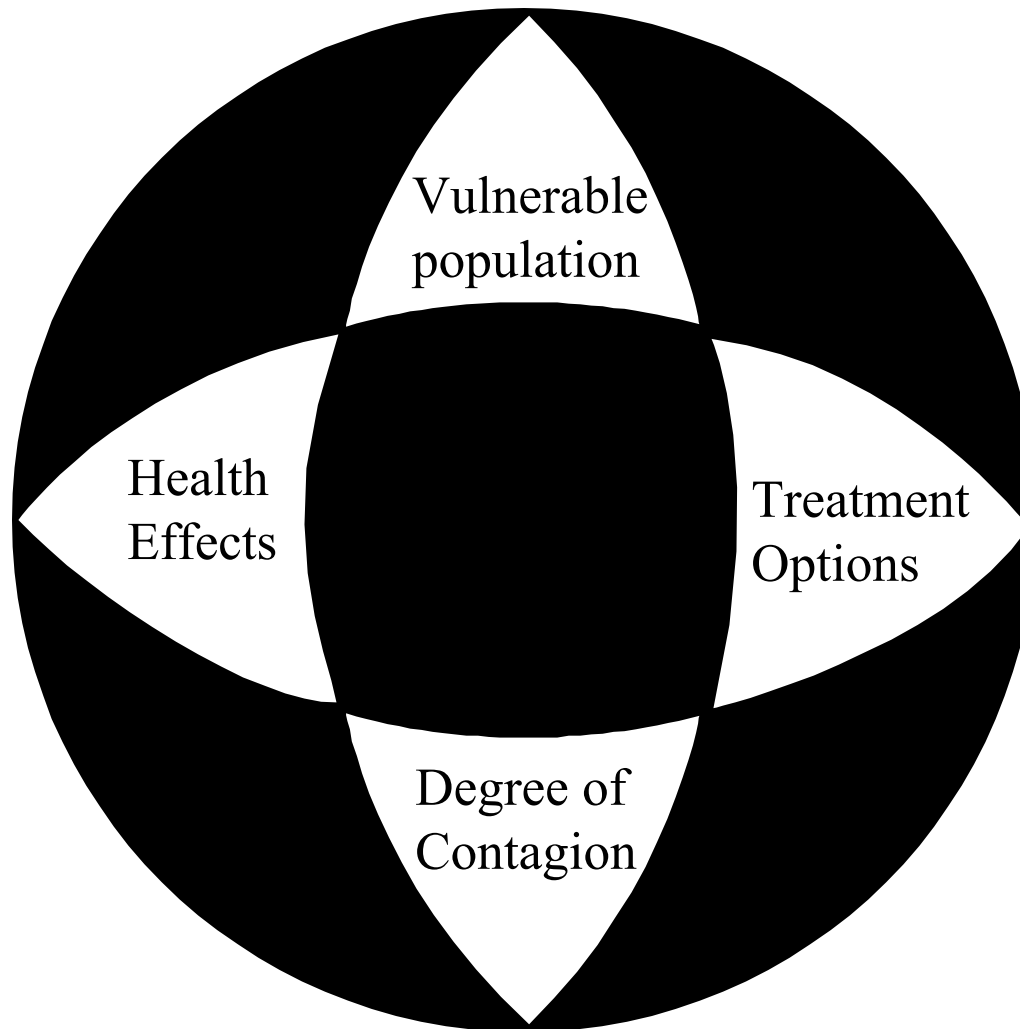
- **CDC grossly underestimates fiscal impacts**
  - Anticipates annualized costs of \$40 million
- **True costs are 3 to 5 times more expensive**
  - CDC estimates called “low ball” numbers
- **Rule doesn’t consider:**
  - Lost lab productivity
  - Increased capital investment costs
  - Lost opportunity costs
  - Lost students and researchers

“It isn’t the number of people killed. It is the potential of people getting killed.”

- Dr. Anthony Fauci, HHS, February 5, 2002
  - » Explaining why the Bush administration is providing an overwhelming increase in funds for bio-terrorism prevention.

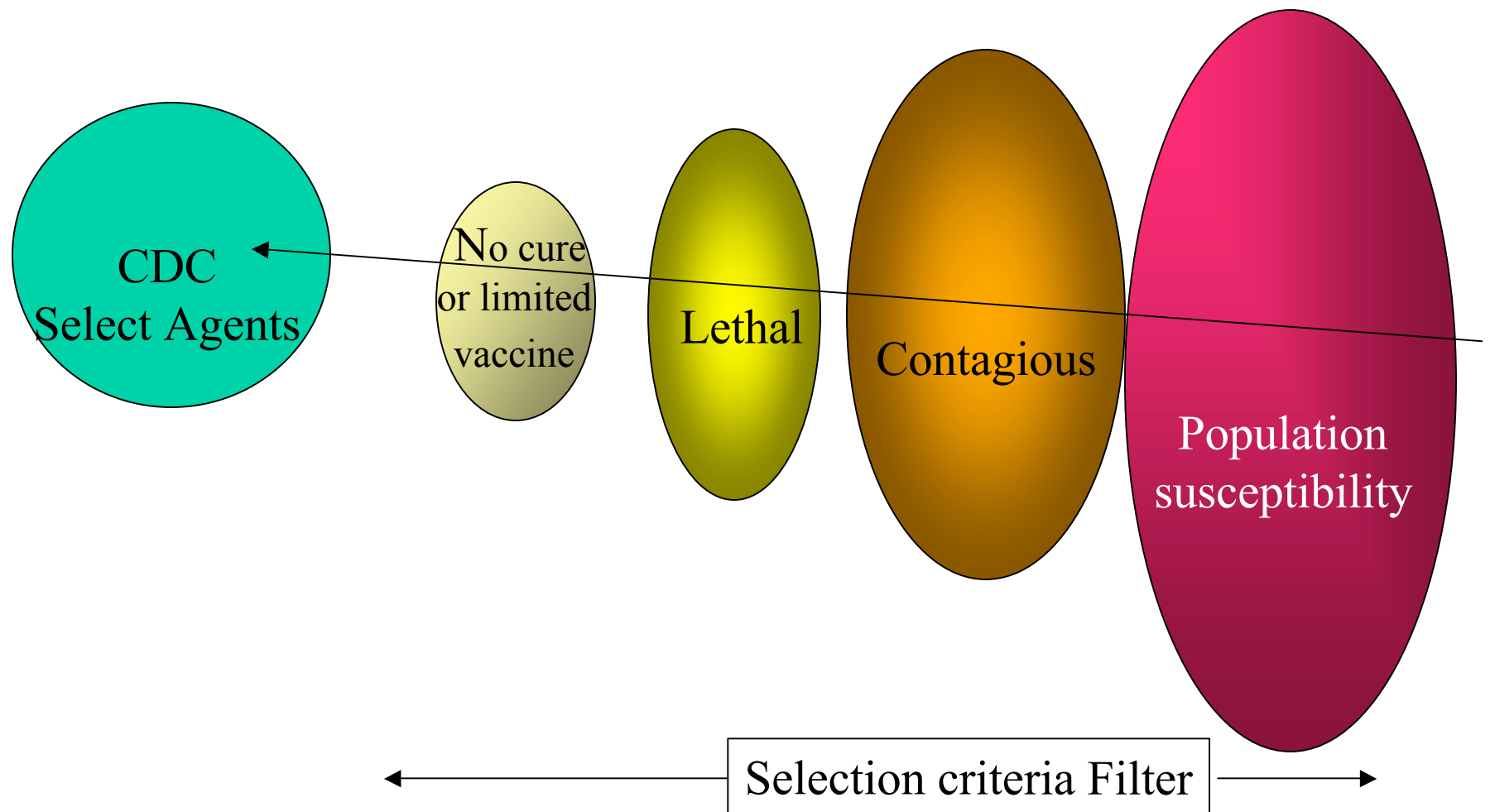
# Step 1: Selecting Select Agents

## Threshold Selection Criteria



# Step 2: Selecting Select Agents

## Applying Selection Criteria



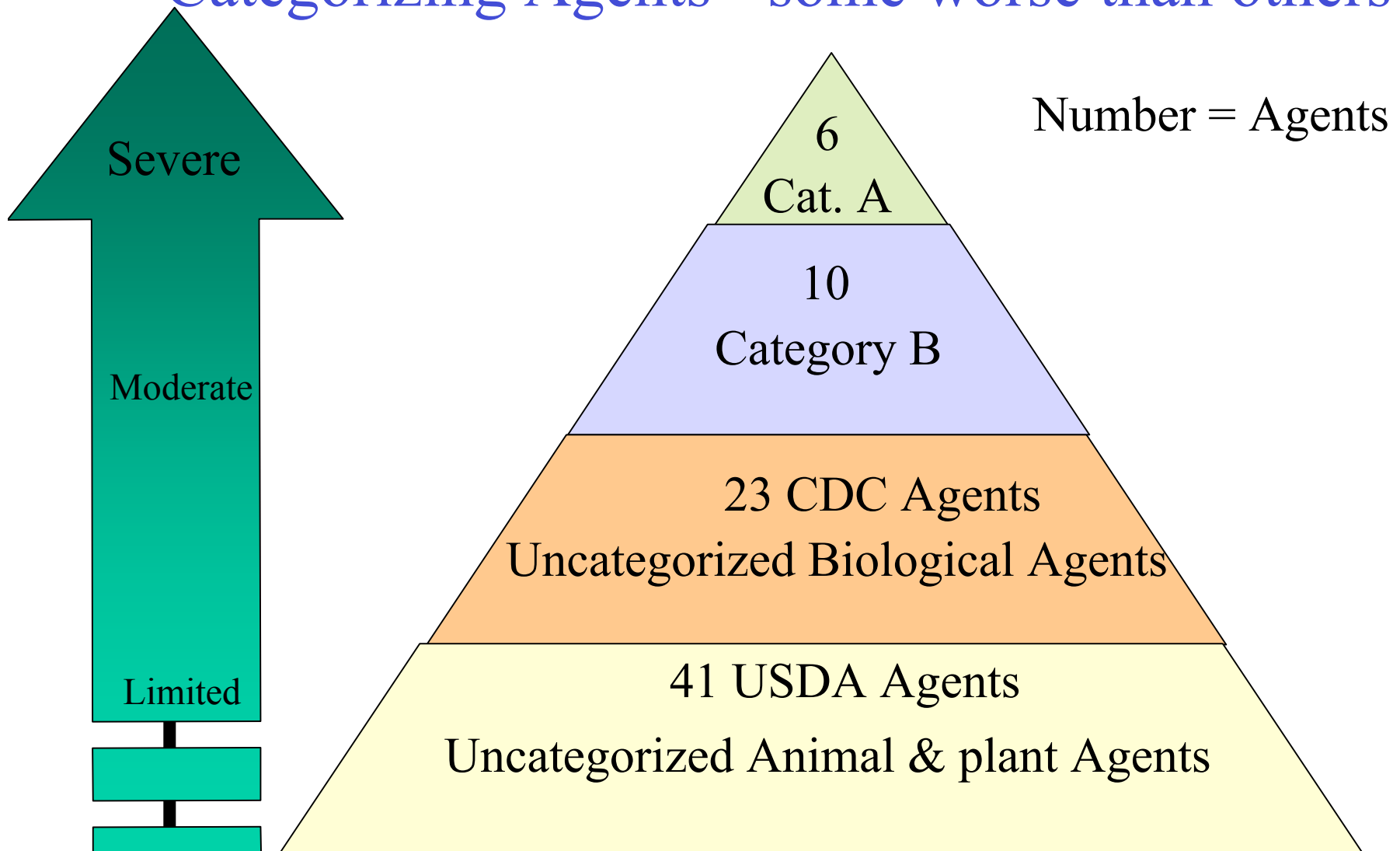
# Step 2: Are Select Agents of Equal risk?

## Risks vary by agent

1. **Public Health Impacts** - Defined by high Morbidity and Mortality
2. **Dissemination Potential** – Defined by person to person transmissibility and potential for widespread production and distribution
3. **Special Public Health Preparation** - Such as stockpiling of vaccines, public education or surveillance and rapid diagnostic lab analysis
4. **Public Perception** – Agents that could cause mass fear and civil disruption.

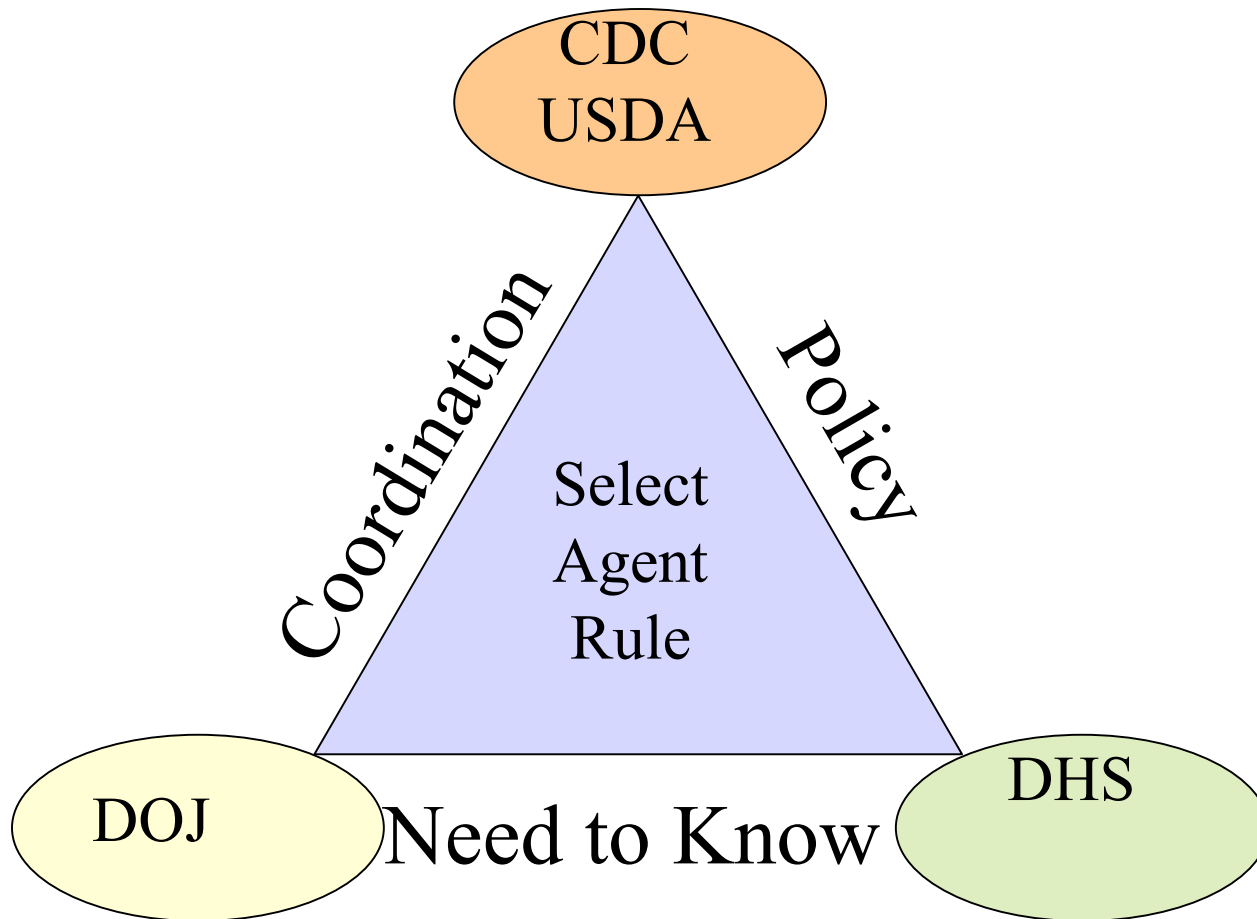
# Step 3: Priority Select Agents:

## Categorizing Agents - some worse than others





# Bio-Medical Research: Who in Government Controls this Work?



# Select Agent Rule: Are Lab Requirements Excessive?

1. Registration for possession, use/transfer
  - Will labs admit possession?
2. Security Risk Assessment
  - Does it stop criminals? Will honest lab workers accept scrutiny?
3. Designation of a Responsible Person
  - Who will accept liability of being in charge?
4. Inventory Tracking and Controls
  - Bio-agents aren't pencils - can't be counted

# Select Agent Rule: Are Lab Requirements Excessive?

(Continued)

## 6. Training and Inspections

- What standards will be expected?

## 7. Notification of theft, loss or release

- How can you tell if a theft has occurred?

## 8. Safety & Security Plans

- Who decides if bio-safety and security is met?

## 9. Emergency Response Plan

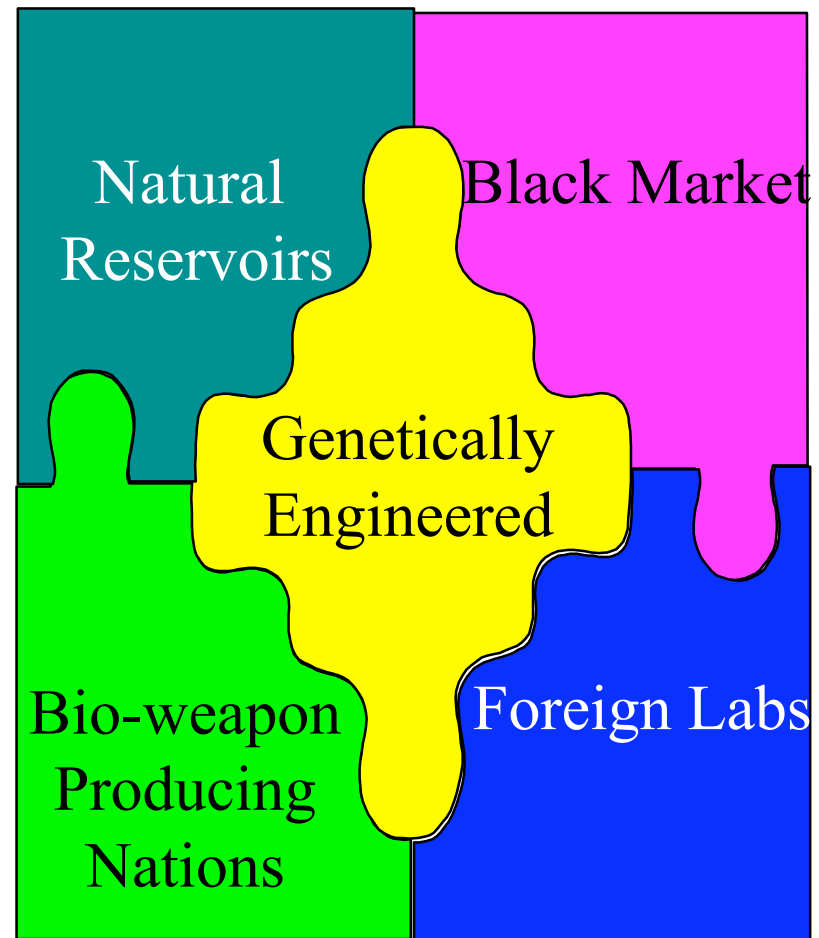
- Will community accept lab activities?

# Do Lab Regulations Eliminate Link to Bio-Terrorism?

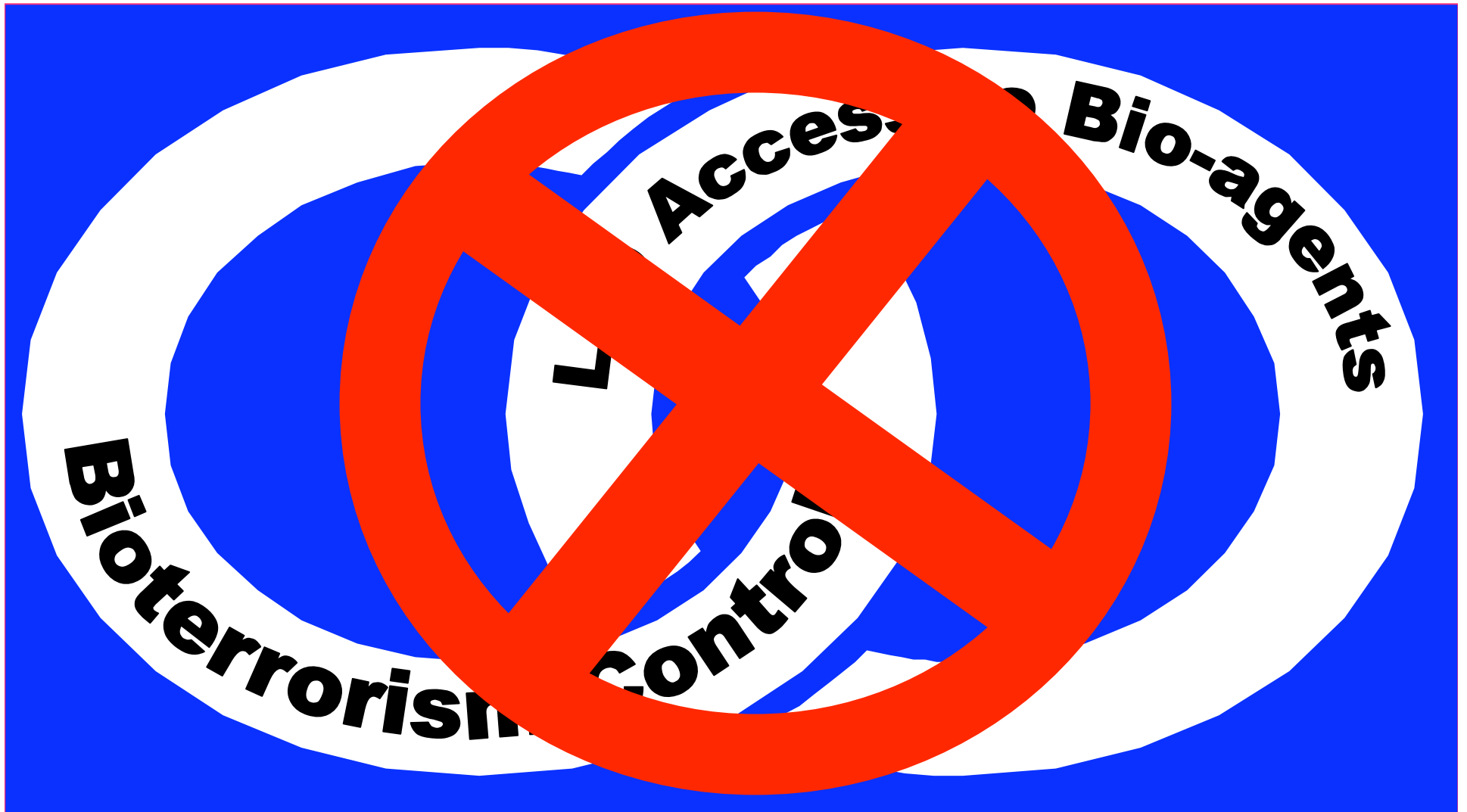


# What Other Sources Exist?

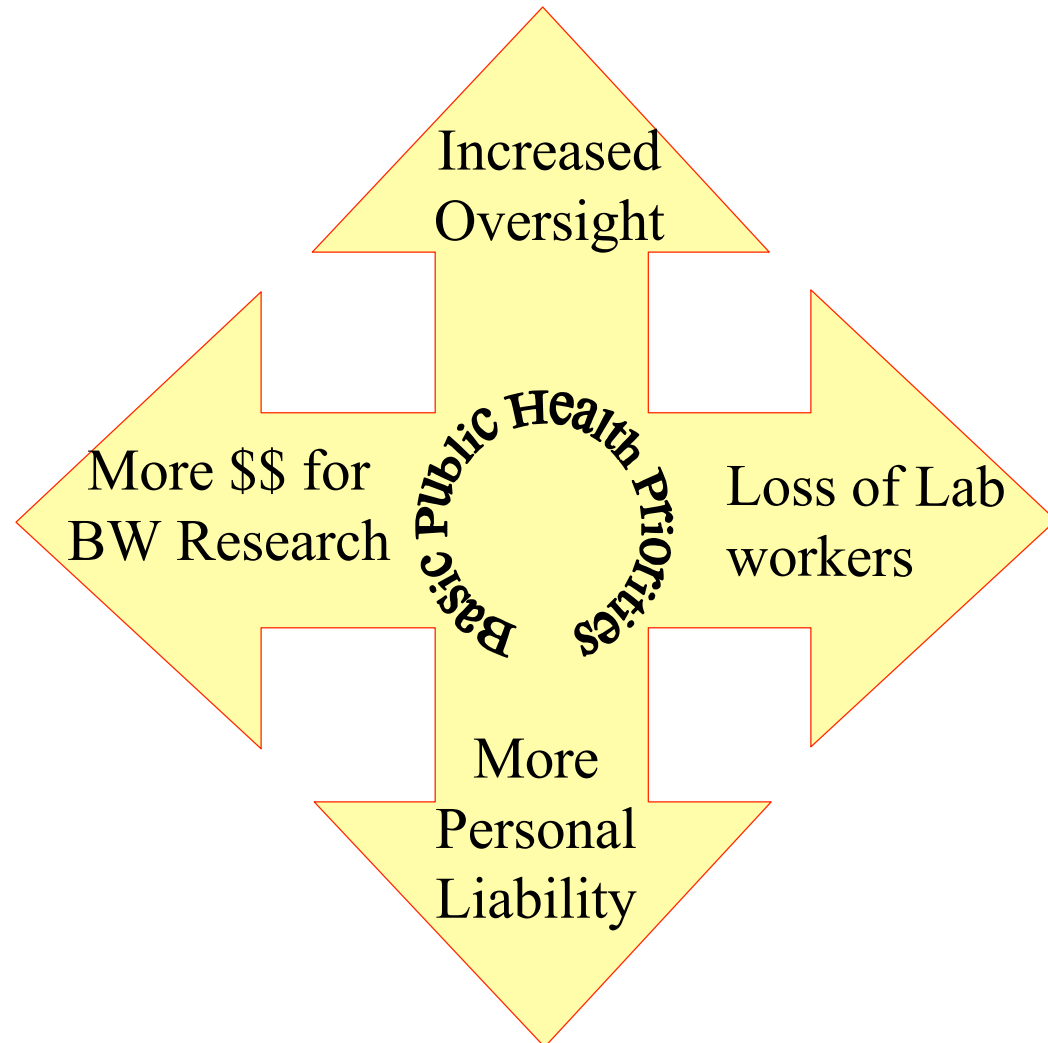
- Natural Reservoirs
  - For some easy access
- Black Market Sources
  - Terrorist group issues
- Foreign Labs
  - Not under Convention
- Bio-weapon Producers
  - Rogue nations
- Genetic Engineering
  - Limited controls exist



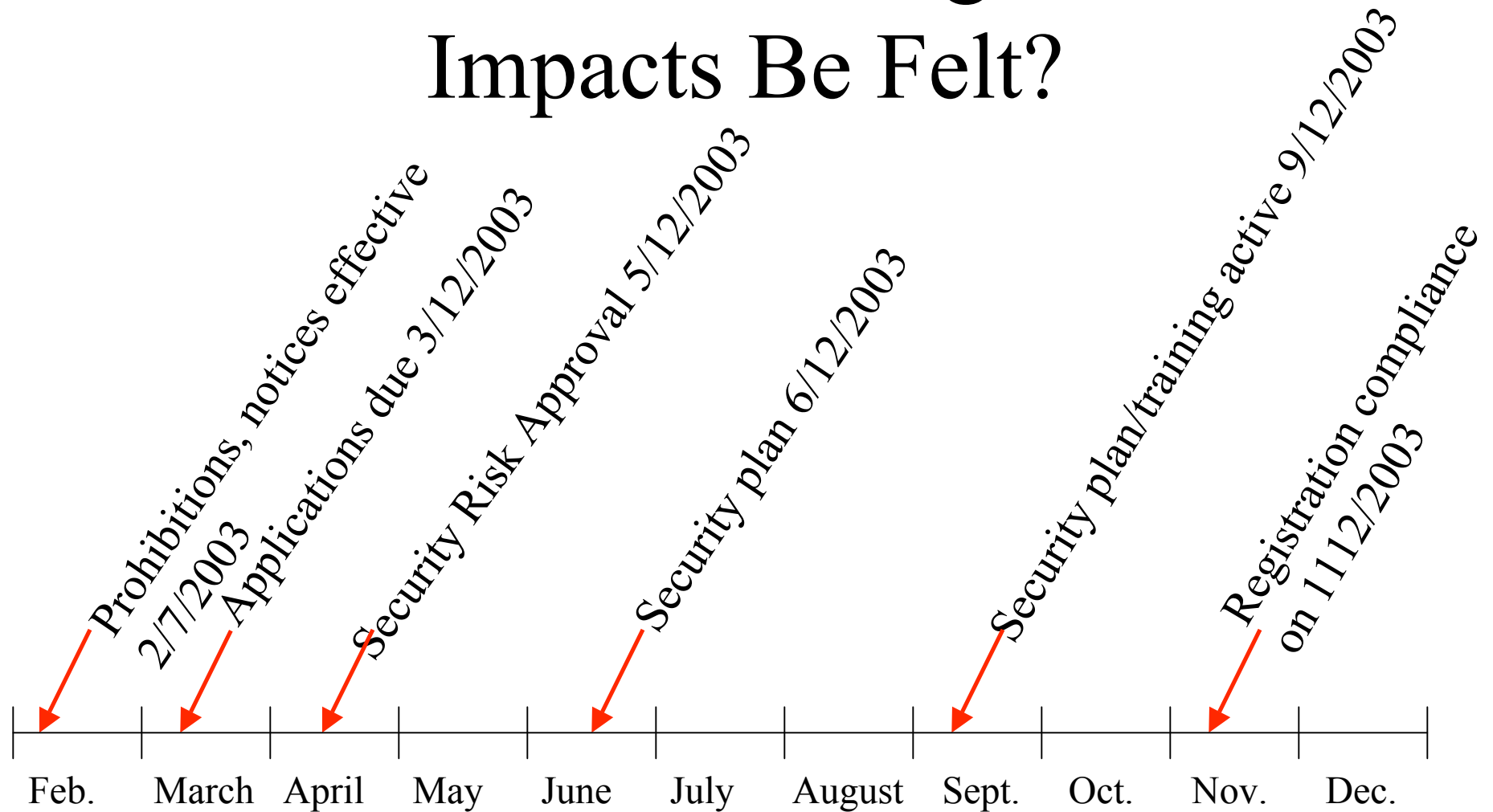
# Do Lab Regulations Eliminate Link to Bio-Terrorism?



# Impacts on Public Health Priorities: Competing Forces



# When Will Select Agent Rule Impacts Be Felt?



Compliance timetable for 2003



# New Lab Bio-Security Considerations

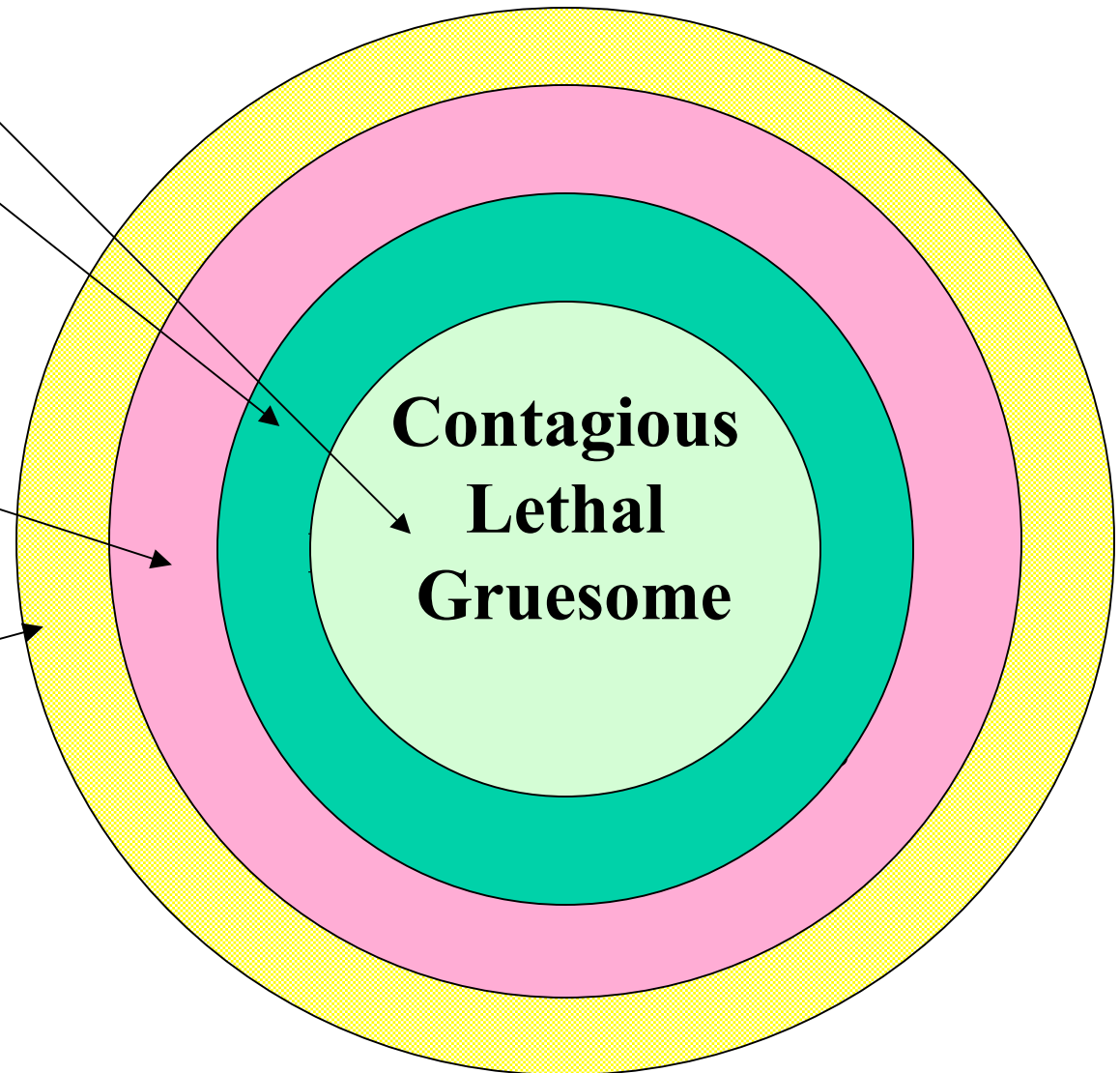
## Risk Assessment Principles

Public Perception Factors

Community Factors

Security Factors

Threat Assessment



# Conclusions

## Getting the Balance Right

- **Priorities:** Bio-medical research priorities affected by focus on BW agents.
- **Regulations:** Controls not commensurate with risks posed by academic/commercial labs
- **Funding:** Increased budgeting for security related public health measures.

# Policy Recommendations

- **Minimize Burdens on Research**
  - Provide training support for academic labs
  - Adopt Performance based security concept
- **Involve Scientists in Decision making**
  - Create Select Agent research advisory committee
- **Minimize Individual Liabilities**
  - Provide due process protections
  - Establish an “Innocent researcher” defense
  - Don’t burden honest researcher